

Directions for use: Information for the user

Otalgan[®]

Active substances: phenazone, procaine hydrochloride
Recommended for children and adults

Read all of this leaflet carefully as it contains important information for you. This medical product is available without prescription. However, you must use Otalgan carefully to get the best results.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- Go and see your doctor if your symptoms worsen or do not improve after two days.
- If you are seriously affected by any of the side effects mentioned or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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1. WHAT IS OTALGAN AND WHAT IS IT USED FOR

Soothing, anti-inflammatory ear drops.

Otalgan is used:

For the local, symptomatic treatment of pain in the external auditory canal, i.e. for external ear infections and for acute middle ear infection. The medical product may be used only if the eardrum is intact.

2. BEFORE YOU USE OTALGAN

Do not take Otalgan

- if you are allergic to pyrazolone (hypersensitivity to medical products containing metamizole, isopropylaminophenazone, propylphenazone or phenazone, for example)
- if you are hypersensitive (allergic) to medical products containing phenylbutazone
- if you suffer from certain metabolic disorders (hepatic porphyria, congenital glucose-6-phosphate dehydrogenase deficiency)
- if you are known to be hypersensitive to any of the ingredients in Otalgan
- if you have a damaged eardrum, inflammation of the auditory canal with damage to the skin.

Take special care with Otalgan

Use Otalgan for the treatment of chronic middle ear infection only under medical supervision.

What should be taken into account in the case of children?

This medical product may be used for children aged under 3 years only under medical supervision.

Using Otalgan with other medical products

Please inform your doctor or pharmacist if you are taking other medical products or have taken them recently, even if it is a non-prescription medical product. Depending on the nature of your illness, your doctor may give you another product to take at the same time as you are using Otalgan.

Avoid taking sulphonamides and benzylpenicillin at the same time as using Otalgan due to the possibility of interaction between the medical products.

Using Otalgan with food and drink

There are no special precautions required.

Pregnancy and lactation

Ask your doctor or pharmacist for advice before taking/applying any medical products.

There are no adequate data from the use of Otalgan in pregnant women and no animal studies have been carried out on the possible effects of active substance combination on pregnancy and on the child's development. For this reason, Otalgan must not be used during pregnancy, unless your treating doctor feels it is absolutely essential. In this instance, you should use Otalgan only for a short period of time and at the lowest dose.

Driving and using machinery

No influence on the ability to drive or use machines has been observed when using Otalgan ear drops.

Given that after this medical product has been applied as directed your auditory canal is plugged with cotton wool, you must not get behind the wheel of a vehicle. This may affect your hearing and therefore, your ability to react in traffic, use machines or work in situations without secure support.

Important information about some of the excipients of Otalgan

One of the other excipients Otalgan contains is glycerol (anhydrous glycerine). Glycerol is a viscous (syrup-like) substance which is produced exclusively from plant oils for this purpose (e.g. coconut oil).

Butylhydroxyanisole may cause locally limited irritation of the skin (e.g. contact dermatitis), irritation of the eyes and mucous membranes.

3. HOW TO APPLY OTALGAN

Always apply Otagan exactly according to the instructions in this leaflet. You should check with your doctor or pharmacist if you are not sure.

Unless otherwise prescribed by your doctor, the usual dosage is:

Age	Single dosage	Total daily dosage
Children up to 14 years	2 – 3 drops	3 – 4 times 2 – 3 drops
Children over 14 and adults	5 drops	3 – 4 times 5 drops

Method of application: application to the ear

Squeeze Otagan ear drops at body temperature (warm up the bottle by holding it in your hand. Do not heat!) into the auditory canal of the affected ear, while lying on your side. Release one drop at a time by lightly squeezing the bottle. Follow the illustrations in Figures 1 and 2 showing how to open and apply the ear drops. Close the bottle immediately after use. You should remain lying on your side for approximately 15 minutes after applying the eardrops so that they can take effect. Then plug your ear loosely with cotton wool. No cotton wool is required to plug your ears after treatment has been completed.

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- 1 Open the security seal on the bottle by turning it in an anticlockwise direction.
 - 2 After opening the bottle, apply the drops in the auditory canal at the dose directed, by squeezing the plastic bottle.
 - 3 After use, close the bottle and store it at normal room temperature.
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Duration of treatment

The normal duration of treatment is 5 days. Treatment may be continued for an unlimited time under medical supervision. Otagan is intended to be used only for short-term, symptomatic analgesia. A doctor must be consulted if the pain does not subside within 2 days of treatment, since earache may be caused by a variety of problems. The same applies if symptoms intensify during treatment.

Medical treatment is required if a fever and/or dizziness occur following inflammation of the ear.

Frequency of application

Three to four applications of the single dose are recommended as a daily dose.

Speak to your doctor or pharmacist if you feel that Otagan's effect is too strong or too weak.

If you apply more Otagan than you should

Overdose or intoxication are unlikely with topical application in the ear. Contact your doctor if you are not sure.

If you forget to apply Otagan

Do not apply a double dose. Apply the ear drops on the next occasion at the specified single dose.

If you stop using Otagan

This can lead to a recurrence of earache because the illness causing the pain has still not been cured.

If you have any further questions on the use of this medical product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medical products, Otagan can have side effects, although not everybody gets them.

The following frequency guidelines are used when assessing side effects:

Very frequent: more than 1 in 10 patients

Frequent: less than 1 in 10, but more than 1 in 100 patients

Occasional: less than 1 in 100, but more than 1 in 1,000 patients

Rare: less than 1 in 1,000, but more than 1 in 10,000 patients

Very rare: less than 1 in 10,000 patients or unknown

Significant side effects or signs you should look out for and measures to take if you are affected by them

If you are affected by any of the side effects mentioned below, stop using Otagan and contact your doctor as soon as possible. Very rare: Hypersensitive reactions such as changes to your skin or nettle rash (urticaria) in the form of itching or swelling of the tissue.

If the eardrum is damaged and/or the auditory canal has been injured, the use of Otagan may cause pain symptoms.

Other possible side effects

If you are seriously affected by any of the side effects mentioned or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE OTALGAN

Keep this medical product out of the reach and sight of children.

Do not use the medical product after the expiry date which is stated on the label/carton. The expiry date refers to the last day of that month.

Storage conditions

Do not store above 25° C. Keep the container closed tightly.

Shelf life after opening the container

Otagan has a shelf life of 12 weeks after the container has been opened for the first time. Do not use Otagan if the contents of the bottle become discoloured after being inadvertently heated above body temperature.

6. FURTHER INFORMATION

What Otagan contains: The active substances are: phenazone 50 mg/g, procaine hydrochloride 10 mg/g.

The other excipients are: butylhydroxyanisole (Ph.Eur.) 0.1 mg/g, glycerol 939.9 mg/g.

What Otagan looks like and contents of the pack: Otagan is a bright, viscous solution. Otagan is available in a pack containing 10 g ear drops/solution (N 1).

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The leaflet was last revised in October 2007.

The following information is intended for doctors and healthcare staff only

Prevent Otalgan ear drops from having any contact with the patient's eyes or nose. If this happens, rinse eyes or nose immediately with lots of water.

An overdose from Otalgan could occur particularly in children if Otalgan is inadvertently ingested orally. If Otalgan is inadvertently ingested orally, the patient's tongue and oral cavity may become numb due to the procaine hydrochloride contained in it, which may cause difficulties in swallowing. In this case, rinse the oral cavity out immediately with lots of water and consult a doctor.